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(54) Title: COATING COMPOSITION FOR TASTE MASKING COATING AND METHODS FOR THEIR APPLICATION AND USE

(57) Abstract: The present invention relates to coating compositions for taste masking and methods for applying the coating compositions to dosage forms to mask the taste of a medicinal substance. The taste masking coating compositions generally include a copolymer of acrylate and methacrylate with a quaternary ammonium group in combination with sodium carboxymethylcellulose and a polyvinyl alcohol-polyethylene glycol copolymer.

WO 2004/052345 A1

INTERNATIONAL SEARCH REPORT

PCT/IB 03/05877

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/58 A61K9/62

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	WO 03/026615 A (THOMAS MARTIN ; LI SHUN-POR (US); LEE DER-YANG (US); MCNEIL PPC INC (U) 3 April 2003 (2003-04-03) paragraph '0098! - paragraph '0100! paragraph '0131! - paragraph '0133! paragraph '0138!	1-62
Y	BASF CORPORATION: "Specification 'Kollicoat IR', Product Number 55554797" BASF CORPORATION, 'Online! 2001, XP002276164 NJ, USA Retrieved from the Internet: URL: http://www.basf.com/pharma 'retrieved on 2004-03-30! the whole document	1-62



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

5 April 2004

Date of mailing of the international search report

23/04/2004

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	<p>PACHIONE R.: "FCE Pharma. Lancamentos desafiam cambio volatil" REVISTA QUIMICA E DERIVADOS, 'Online! no. 408, September 2002 (2002-09), XP002276165 SAO PAULO, BRASIL Retrieved from the Internet: URL: http://www.quimica.com.br/revista/qd408/fcel.htm > 'retrieved on 2004-04-05! See last paragraph the whole document</p> <p>-----</p>	1-62
Y	<p>US 6 136 347 A (BUECHELER MANFRED ET AL) 24 October 2000 (2000-10-24) cited in the application column 4, line 55 - column 5, line 21 column 5, line 28 - column 6, line 6 examples</p> <p>-----</p>	1-62
Y	<p>US 6 106 861 A (DEMICHELIS ALAIN GILLES ET AL) 22 August 2000 (2000-08-22) cited in the application column 2, line 66 - column 3, line 25 examples</p> <p>-----</p>	1-62

INTERNATIONAL SEARCH REPORT

PCT/IB 03/05877

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claim 62 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

PCT/IB 03/05877

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 03026615	A	03-04-2003	US 2003068367 A1	10-04-2003
			US 2003072799 A1	17-04-2003
			US 2003086973 A1	08-05-2003
			US 2003070903 A1	17-04-2003
			US 2003124183 A1	03-07-2003
			BR 0206061 A	13-01-2004
			BR 0206062 A	13-01-2004
			BR 0206086 A	23-12-2003
			CA 2446759 A1	03-04-2003
			CA 2446760 A1	03-04-2003
			CA 2447984 A1	03-04-2003
			NO 20032362 A	14-07-2003
			NO 20032363 A	23-07-2003
			NO 20032364 A	25-07-2003
			WO 03028990 A1	10-04-2003
			WO 03026624 A1	03-04-2003
			WO 03026625 A1	03-04-2003
			WO 03026626 A2	03-04-2003
			WO 03026628 A2	03-04-2003
			WO 03026612 A2	03-04-2003
			WO 03026613 A1	03-04-2003
			WO 03026614 A1	03-04-2003
			WO 03026615 A2	03-04-2003
			WO 03026629 A2	03-04-2003
			WO 03026630 A1	03-04-2003
			WO 03026627 A1	03-04-2003
			WO 03026616 A1	03-04-2003
			US 2003219484 A1	27-11-2003
			US 2003232082 A1	18-12-2003
			US 2003232083 A1	18-12-2003
			US 2004018327 A1	29-01-2004
			US 2003235616 A1	25-12-2003
			WO 03028618 A2	10-04-2003
			US 2003228368 A1	11-12-2003
			US 2003229158 A1	11-12-2003
			WO 03028619 A2	10-04-2003
			WO 03028989 A1	10-04-2003
			US 2003217908 A1	27-11-2003
			WO 03028620 A1	10-04-2003
US 6136347	A	24-10-2000	DE 4200821 A1	22-07-1993
			US 5695784 A	09-12-1997
			AT 186212 T	15-11-1999
			AU 670763 B2	01-08-1996
			AU 3113893 A	22-07-1993
			CA 2087146 A1	16-07-1993
			CN 1074603 A ,B	28-07-1993
			CZ 9203720 A3	11-08-1993
			DE 59309858 D1	09-12-1999
			DK 551820 T3	25-04-2000
			EP 0551820 A1	21-07-1993
			ES 2141117 T3	16-03-2000
			GR 3032382 T3	27-04-2000
			HK 1005987 A1	12-05-2000
			HU 64693 A2	28-02-1994
			HU 211154 B3	30-10-1995
			IL 104362 A	15-04-1997
			JP 5255072 A	05-10-1993

INTERNATIONAL SEARCH REPORT

PCT/IB 03/05877

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 6136347	A		MX 9207630 A1 NZ 245658 A PL 297399 A1 RU 2110255 C1 SK 372092 A3 ZA 9300234 A	30-07-1993 24-02-1995 09-08-1993 10-05-1998 10-05-1995 16-08-1993
US 6106861	A	22-08-2000	FR 2766089 A1 AT 208616 T AU 708197 B2 AU 4930197 A AU 8865998 A BR 9811803 A CA 2296710 A1 CN 1264299 T DE 69802543 D1 DE 69802543 T2 DK 1003484 T3 EP 0896818 A1 EP 1003484 A1 ES 2167921 T3 WO 9904763 A1 HU 0003691 A2 JP 3190299 B2 JP 11035450 A NZ 502228 A PT 1003484 T SI 20059 A TR 200000139 T2	22-01-1999 15-11-2001 29-07-1999 04-02-1999 16-02-1999 19-09-2000 04-02-1999 23-08-2000 20-12-2001 22-08-2002 25-02-2002 17-02-1999 31-05-2000 16-05-2002 04-02-1999 28-04-2001 23-07-2001 09-02-1999 29-06-2001 31-05-2002 30-04-2000 21-09-2000